



SERIAL NO. 09/933,708  
ATTY. No.: 54719.000028

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Thomas PICCARIELLO et al

Serial Number: 09/933,708

Filed: August 22, 2001

For: ACTIVE AGENT DELIVERY SYSTEMS AND METHODS FOR PROTECTING  
AND ADMINISTERING ACTIVE AGENTS

)  
)  
) Group Art Unit: 1653  
)  
) Examiner: Unassigned  
)  
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)

INFORMATION DISCLOSURE STATEMENT

Director of the Patent and Trademark Office  
Washington, D.C. 20231

Sir:

In accordance with 37 C.F.R. §§ 1.97 and 1.98, and in compliance with the duty of disclosure set forth in 37 C.F.R. § 1.56, applicants are submitting herewith copies of the references listed on the attached Form PTO/SB/08A for consideration and to be made of record herein by the U.S. Patent and Trademark Office in the above-captioned application.

Consideration of the foregoing plus the prompt return of a copy of the enclosed Form PTO/SB/08A with the Examiner's initials in the left column in accordance with MPEP 609 are respectfully requested.

Applicants' submission of the Information Disclosure Statement shall not be construed as an admission that the cited references are prior art to the present invention, or that the cited references qualify as printed publications. The submission of this IDS also shall not be construed as a representation that a prior art search has been performed.

In accordance with 37 C.F.R. § 1.97(b), this Information Disclosure Statement is submitted prior to issuance of a first Office Action. Therefore, it is respectfully submitted that no fee is required for consideration of this information. However, in the event any fee is deemed necessary, the Commissioner is authorized to charge the undersigned's Deposit Account No. 50-0206.



21967

PATENT TRADEMARK OFFICE

Respectfully submitted,

HUNTON & WILLIAMS

Dated: March 26, 2003

By: 

Jeffrey T. Perez  
Registration No. 52,110

HUNTON & WILLIAMS  
1900 K Street, N.W., Suite 800  
Washington, DC 20006-1109  
Tel: (202) 955-1500  
Fax: (202) 778-2201

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09/933,708

August 22, 2001

Thomas PICCARIELLO et al.

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<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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Sheet **2** of **5**

## **Complete if Known**

|                        |                           |
|------------------------|---------------------------|
| Application Number     | 09/642,820                |
| Filing Date            | August 22, 2000           |
| First Named Inventor   | Thomas PICCARIELLO et al. |
| Group Art Unit         | 1653                      |
| Examiner Name          | Jeffrey E. RUSSEL         |
| Attorney Docket Number | 54719.000016              |



## **OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS**

| Examiner Initials * | Cite No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T <sup>2</sup> |
|---------------------|-----------------------|---|----------------|
|                     | P49                   | CANARIS, G., "The Colorado Thyroid Disease Prevalence Study," Archives Internal Medicine Articles and Abstracts, Vol. 160, No. 4 (2000).  |                |
|                     | P50                   | BUNEVICIUS, R., "Effects of Thyroxine as Compared with Thyroxine Plus Triiodothyronine in Patients with Hypothyroidism," <i>The New England Journal of Medicine</i> , Vol. 340, No. 6 (1999).   |                |
|                     | P51                   | TOFT, A., "Thyroid Hormone Replacement -- One Hormone or Two?," <i>The New England Journal of Medicine</i> , Vol. 340, No. 6 (1999).  |                |
|                     | P52                   | PADE, V., et al., "Link Between Drug Absorption Solubility and Permeability Measurements in Caco-2 Cells," <i>Journal of Pharmaceutical Sciences</i> , Vol. 87, No. 12 (1998).  |                |
|                     | P53                   | OH, D., et al., "Estimating the Fraction Dose Absorbed from Suspensions of Poorly Soluble Compounds in Humans: A Mathematical Model," <i>Pharmaceutical Research</i> , Vol. 10, No. 2 (1993).   |                |
|                     | P54                   | AMIDON, G., et al., "A Theoretical Basis for a Biopharmaceutic Drug Classification: The Correlation of <i>in Vitro</i> Drug Product Dissolution and <i>in Vivo</i> Bioavailability," <i>Pharmaceutical Research</i> , Vol. 12, No. 3 (1995).                    |                |
|                     | P55                   | Presentation to Knoll Pharmaceutical, April 10, 2000.   |                |
|                     | P56                   | Investment Banking Presentation, March 27-31, 2000  |                |
|                     | P57                   | Pharma Presentation, March 27-31, 2000, New York, NY.   |                |
|                     | P58                   | Deutsche Banc Alex Brown 2000 Health Care Conference Presentation, May 10, 2000, Baltimore, MD.   |                |
|                     | P59                   | April 7, 2000, Letter to Credit Suisse First Boston Corporation   |                |

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Signature

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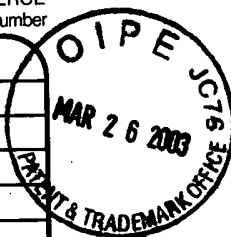
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Sheet 3 of 5

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| Attorney Docket Number | 54719.000016              |



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|---------------------|-----------------------|---|----------------|
|                     | P60                   | April 7, 2000, Letter to Chase, Hambrecht and Quist   |                |
|                     | P61                   | April 7, 2000, Letter to Banc of America Securities, LLC  |                |
|                     | P62                   | April 7, 2000, Letter to Johnson & Johnson  |                |
|                     | P63                   | April 7, 2000, Letter to AstraZeneca LP   |                |
|                     | P64                   | April 7, 2000, Letters to Bear, Stearns & Company, Inc.   |                |
|                     | P65                   | Bankers Presentation, March 27-31, 2000   |                |
|                     | P66                   | Pharmaceutical Presentation, March 27-31, 2000  |                |
|                     | P67                   | KPMG Auditors' Report, March 12, 1999   |                |
|                     | P68                   | Final Report, Study Completion Date June 25, 1998   |                |
|                     | P69                   | Investment Banking Presentation, March 27-31, 2000  |                |
|                     | P70                   | Pharmaceutical Presentation, March 27-31, 2000  |                |

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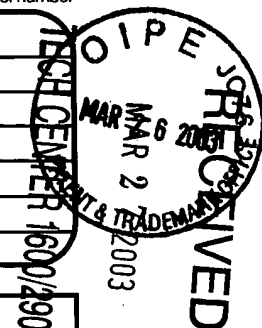
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Sheet 4 of 5

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|------------------------|--------------------------|---|----------------|
|                        | P71                      | Deutsche Banc Alex Brown 2000 Health Care Conference Presentation, May 10, 2000, Baltimore, MD.   |                |
|                        | P72                      | Investment Banking (short) Presentation, April 27, 2000   |                |
|                        | P73                      | Investment Banking (long) Presentation, April 27, 2000  |                |
|                        | P74                      | Banc of America Presentation  |                |
|                        | P75                      | Pharma Presentation, April 2000   |                |
|                        | P76                      | AstraZeneca Presentation  |                |
|                        | P77                      | "Promise of Polythroid," Presentation, March 2000   |                |
|                        | P78                      | "Introducing Polythroid," Presentation, March 2000  |                |
|                        | P79                      | Investment Banking Presentation   |                |
|                        | P80                      | Pharma Presentation, March-April  |                |
|                        | P81                      | Deutsche Banc Alex Brown 2000   |                |

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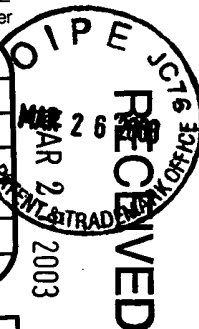
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Sheet 5 of 5

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| Attorney Docket Number | 54719.000016              |

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|---------------------|-----------------------|---|----------------|
|                     | P82                   | August 31, 1999 Presentation to Scios, Inc.   |                |
|                     | P83                   | February 2000 Presentation to Andrx   |                |
|                     | P84                   | March 15, 2000 Presentation to BASF   |                |
|                     | P85                   | Original Presentation to BASF   |                |
|                     | P86                   | February 10, 2000 Lotus Presentation  |                |
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